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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,795	06/25/2000	BRIAN C. KELLER	270142000300	4731

7590 07/02/2002

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EXAMINER

HENDRICKS, KEITH D

ART UNIT

PAPER NUMBER

1761

DATE MAILED: 07/02/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/530,795	KELLER ET AL. <i>Off II</i>
	<b>Examiner</b>	<b>Art Unit</b>
	Keith Hendricks	1761

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 26 March 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 15-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 15-23 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION*****Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 19-27 have been renumbered as 15-23.

***Claim Rejections - 35 USC § 112***

- i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The ranges recited in the instant claims are not found in, or supported by, the original specification. The ranges of “about 0.1% to about 50%” (claim 15), “about 0.05% to about 30%” (claim 21), and “between about 50nm and about 100nm” (claim 23), are not supported for numbers outside of the specifically-disclosed ranges, for example, due to the ambiguity of the added term “about”.

Further, the range of “0.2% to 2%” (claim 17), does not find support for the selection of these particular endpoints from the disclosed ranges. The range of “0.2% to 2%”, with regard to the phospholipid content, is improper, even with respect to the passing reference at page 2 of the specification, which states that “phospholipids and cholesterol contribute 1-2% of total fat” to human milk. This does not equate to, nor support, the range of phospholipids (alone) in concentrations of “0.2% to 2%”. *[Kew]*

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Applicant has provided no guidance, support or explanation as to the (improper) addition of these ranges. Deletion of the rejected new subject matter is required.

ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is suggested that the phrase “bilayer forming lipid”, be amended to “bilayer-forming lipid”, to more clearly define the invention. This was addressed in the previous Office action.

It is unclear as to how the simple two-component liposome may itself be “useful as an infant formula.” The specification discloses the use of such liposomes within infant formulas, with other infant formula components.

Claims 15 and 18-20 recite improper Markush-type language. The selection of multiple components of a set list, should either be in the form of (a) a closed set: “*selected from the group consisting of A, B, C and D*”, or (b) an open set: “*comprising A, B, C, or D*.“” This was also addressed in the previous Office action.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this

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application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 15-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehansho et al.

Applicant's arguments filed March 26, 2002, have been fully considered but they are not persuasive. At page 4 of the response, applicants state that "the present claims are limited to liposomal-based infant formula preparations." This is not deemed persuasive, as the claims simply state that the preparations are "useful as an infant formula", and are not limited to an "infant formula", *per se*. Further, it is unclear as to why the chocolate milk formulation of Mehansho would not serve this purpose.

Applicants state, at page 5, that "Mehansho does not disclose preparations which would closely resemble the composition of human milk and would be useful as an infant formula." However, no rationale or support for this statement is provided. The phospholipid concentration is addressed at columns 6-7 of the reference, where it is stated that the edible carrier may be a liposome, and may serve to carry a divalent mineral salt, where "the ratio of divalent mineral salt to edible carrier can vary widely, but is typically in the range of from about 1:1 to about 1:500." This reads upon the lipid component (i.e. that which is the liposome. See applicants' own specification, pg. 3) in a concentration of "50%".

Again, regarding the size of the liposomes (claim 23), this is considered to be an inherent property of the specifically disclosed compositions of the reference, absent any clear and convincing evidence and/or arguments to the contrary. If the same standard liposome structure is provided, as well as the same micronutrient components within, then it must be presumed and expected that the reference provides a composition of the two having a size within the instantly-claimed range.

Applicants' comments with regard to the inherent properties of the disclosed structures are not deemed persuasive. Applicants state that the feature must necessarily be present, and must "naturally flow" from the disclosure. This is agreed upon. However, applicants continue, by misconstruing this case law, as implying that the inherent feature must somehow be "fairly apparent", "recognized by one of skill in the art", or even explicitly disclosed in the reference. This is not a fair assessment of the prevailing case law, nor of the practice of the Office. A reasonable explanation has been provided (see above) as to why the reference meets the claimed invention, and thus the burden shifts to applicant to demonstrate otherwise. If the case law were such that the reference was to disclose the "recognizable" property, then this would be tantamount to the reference specifically disclosing the property. Simply because the reference did not state the specific size of the liposomes, or that they were blue in color, or some other property, does not mean that they were not of this nature. A reasonable interpretation of the

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reference has been provided and logically supported. Applicant may not obtain a patent on a known product, regardless of the characterization of said same product.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached at (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



KEITH HENDRICKS  
PRIMARY EXAMINER